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EXAMINER
HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,714	SEWALT ET AL.	
	Examiner	Art Unit	
	Keith Hendricks	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: any actual required steps which would result in the claimed invention. Parts (a) and (b) recite adding a component to the proteinaceous product "in an amount between 0 ppm and up to about 10,000ppm [or 40,000 ppm]", which encompasses the addition of these components at zero ppm; i.e., it encompasses no additions. In the situation of adding zero amount of reducing agent and chaotroph, the claim does not specifically require any positive, active method step. Similarly, dependent claims 2-8 and 10-11 do not provide any further limiting steps, and are thus rejected as well.

Independent claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The claim encompasses embodiments where there are no physical elements present, and thus it is impossible to ascertain what is, and is not, included in the claim. Initially, the claim is directed to "a composition for treating a proteinaceous product", but does not actually include or require the presence of the proteinaceous product (it is recognized that logically the protein would not be part of the claimed invention of a composition *for the treatment* of such). However, parts (a) and (b) recite either a reducing agent or a chaotroph component "in an amount between 0 ppm and up to about 10,000ppm [or 40,000 ppm] of the proteinaceous product", which encompasses the presence of these components at zero ppm; i.e., it encompasses the presence of neither either a reducing agent or a chaotroph component. Therefore, given that the claim may be reasonably interpreted to *not* include the protein, a reducing agent or a chaotroph, the claim is incomplete for omitting (any and all) essential elements. Similarly, dependent claims 13-27 do not provide any further limiting components, and are thus rejected as well.

Claims 12-27 are indefinite for the recitation of the components being present in amounts relative to the proteinaceous product (for example, "...10,000ppm of the proteinaceous component"). The claim does not specifically include or require the presence of the proteinaceous product, and thus it would be impossible for one skilled in the art to determine an amount of another component (for example, the reducing agent or chaotroph) in relation to a protein component which does not (and should not) exist within the composition. In other words, the amounts of the reducing agent, chaotroph, etc. cannot be determined *relative to the proteinaceous product*, as the proteinaceous product is not an actual part of the composition. Claim 21 does not further limit the claim(s) from which it depends, as the location and conditions of the protein are irrelevant to the claimed invention, namely the composition. Note that this rejection is distinct and irrespective of the above rejection regarding omitting essential elements.

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that they fail to point out what is included or excluded by the claim language. These are omnibus type claims.

** Examiner's NOTE: Upon amendment of the claims, applicant is cautioned against the introduction of new matter, such as the modification of the recited ranges and their endpoints without proper support in the specification.

Claims 20 and 23 are indefinite for the recitation of the phrase "A method as defined in claim 19 [or 22]." Claims 19 and 22 are directed to compositions, and thus the metes and bounds of the claimed invention are unclear.

Claims 2-3, 6, 8, 11, 13-15, 18, 20 and 23 are indefinite for the recitation of the general phrase "selected from the group comprising... and ...". The recitation of a selection from a group of elements in a claim should comply with accepted U.S. Patent practice with regard to the recitation of Markush grouping of claim elements. Phrases using "comprising" are open sets, and should recite elements in the alternative (i.e. "**comprising** A, B, C **or** D"), whereas closed sets ("consisting of") should recite elements as "selected from the group **consisting of** A, B, C **and** D."

Claim 28, part (d) is indefinite for the recitation of the phrase "selected from the group consisting of TBHQ, BHA, BHT, propyl gallate, carnosic acid, plant extracts, **or** any inert gas that will exclude

oxygen, **preferably** nitrogen **or** carbon dioxide." See the above paragraph with respect to proper Markush listing of claim elements.

Further, claim 28 is improper for the recitation of the term "**preferably** nitrogen or carbon dioxide." The phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are actually part of the claimed invention. See MPEP § 2173.05(d).

(Note that all other recitations in claim 28, parts (a)-(c) and (e), are proper.)

Claim 28 is indefinite for the recitation of the phrase "or any inert gas that will exclude oxygen." It is unclear as to which gases are encompassed by the claim, due to the phrase "that will exclude oxygen." It is unclear as to how oxygen is to be "excluded", whether this is completely or partially, and whether all inert gases are encompassed by this phrase.

Claim Objections

Claims 2, 13 and 28 are objected to because of the following informalities:

The term "dithiothreietol" should be spelled "dithiothreitol."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Buchanan et al. (US PAT 5,952,034, of record).

Buchanan et al. disclose a method of "increasing the digestibility of food proteins by thioredoxin reduction", where various protein-containing materials such as milk proteins, and cereal grains which contain gliadins and glutenins that affect dough and baked goods, are reduced by the use of thiol redux proteins. "More particularly, the invention involves use of thioredoxin and glutaredoxin to reduce

gliadins, glutenins, albumins and globulins to improve the characteristics of dough and baked goods and create new doughs and to reduce cystine containing proteins such as amylase and trypsin inhibitors so as to improve the quality of feed and cereal products" (col. 1, ln. 25-30). "The invention also involves using thioredoxin to decrease the allergenicity of food allergens and to increase the proteolysis of food proteins and the digestibility of food", including milk proteins.

> Column 56 states:
>
> The invention provides a method for chemically reducing the disulfide bonds in major food proteins particularly food allergen proteins and for decreasing or eliminating the allergenicity that occurs when foods containing those proteins are ingested. The invention also provides a method for increasing the digestibility of food proteins and therefore food. The disulfide bonds are reduced to the sulfhydryl (SH) level by thioredoxin. The other major cellular thiol reductant, glutathione, was inactive in this capacity. The proteins are allergenically active in the oxidized (S--S) state; when treated with thioredoxin (SH state), they lose allergenicity. Thioredoxin achieves this reduction when activated (reduced) either by NADPH via the enzyme NADP-thioredoxin reductase, (physiological conditions) or by dithiothreitol, a synthetic chemical reductant.

"A reductant of thioredoxin used herein can include lipoic acid or a reduction system such as NADPH in combination with NADP thioredoxin reductase (NTR). The reductant of glutaredoxin can include reduced glutathione in conjunction with the reduction system NADPH and glutathione reductase. NADPH can be replaced with an NADPH generator or generator composition" (col. 10-11).

"Dithiothreitol (DTT) and the reduced forms of thioredoxin and lipoic acid are dithiol reductants as opposed to monothiol reductants like 2-mercaptoethanol and glutathione. DTT is a synthetically prepared chemical agent, whereas thioredoxin and lipoic acid occur within the cell" (mid-col. 52).

Columns 13 and 37 teach the use of thioredoxin *h* (TRX *h*) from wheat.

At column 65, in order to obtain a sequence analysis of BLG (beta-lactoglobulin), a laboratory experiment was produced, where at one stage, "the pooled extracts were dried, dissolved in a minimal volume of 6 M guanidine HCl-Tris, pH 8.2. Extracted peptides were then reduced with dithiothreitol (DTT) and alkylated with iodoacetamide." This demonstrates the use of both a reducing agent (dithiothreitol) and a chaotroph (guanidine hydrochloride).

Finally, column 7, lines 30-35 state that "reductive inactivation of snake toxins in vitro by incubation with 1% beta-mercaptoethanol for 6 hours and incubation with 8M urea plus 300 mM .beta.-mercaptoethanol has been reported in the literature (Howard, B. D. et al. (1977) Biochemistry 16:122-125; Yang, C. C. (1967) Biochim. Biophys. Acta. 133:346-355)." This demonstrates that the use of both

a reducing agent (beta-mercaptoethanol) and a chaotroph (urea) to treat a proteinaceous product was known.

Thus the broadly-claimed invention is anticipated by the reference. The reference discloses the treatment of protein-containing products by the use of (a) a reducing agent such as DTT, (b) a chaotroph, (c) an enzyme such as TRX *h* or thioredoxin reductase, and (d) "a material which assists in blocking of free sulfhydryl groups", such as oxidized (i.e. reduced) glutathione, and various combinations thereof.

NOTES:

- Regarding the dependent claims as directed to the addition/inclusion of "a material to assist in maintaining the reducing condition in the proteinaceous product," it is noted that none of these claims actually *require* the presence of these materials, as the claims state that such materials may be present "in an amount up to about 1000 ppm." See also the rejections under 35 USC 112 2nd paragraph, above.
- With regard to the applicability of the prior art, instant claim 21 does not further limit the claim(s) from which it depends, as the location and conditions of the proteinaceous product are irrelevant to the claimed invention, namely the composition. The claims do not specifically include the proteinaceous product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prusiner et al. (US PAT 6,720,355).

Prusiner et al. generally disclose an antiseptic composition to "inactivate the infectability of infectious proteins such as prions under relatively mild conditions" (col. 3, ln. 19-23) comprising an aqueous solvent, an acid, and an active component which renders infectious prions non-infectious. "The composition of the invention will vary due to the large number of different acids and inactivating agents

that can be used" (col. 4, ln. 16-19). "Another aspect of the invention is the use of a wide range of protein denaturants at low pH to inactivate prions" (top col. 5). "Another aspect of the invention is the use of the claimed compounds in livestock feed. This can prevent the transmission of prions from livestock to humans by eliminating prions from the livestock before slaughter (col. 5, ln. 25-28). Columns 6-7 describe the various active components which may be effectively utilized in the compositions and methods. "Preferred compounds that act as an active component for prions include SDS, urea, and a wide range of protein denaturants including guanidine and thiocynate as well as various branched polycations" (col. 6, ln. 50-52). Recited agents also include urea, guanidine hydrochloride, dithiothreitol (DTT), chaotropes, various organic solvents and detergents, and branched polycations such as polyamidoamines. Various example formulations are provided at columns 12-17. Columns 18-19 specifically describe the addition of the disclosed compositions to livestock feedstuffs, where "the compounds of the invention can be combined with plant-derived materials used in livestock feed in order to render prions non-infectious and/or prevent or treat prion infections in the animal eating the feed. More particularly, the compounds of the present invention can be added to livestock feed or feedstuffs used to feed any type of livestock" (col. 18, ln. 50-56). "Generally, when the term 'feedstuff' is used with respect to the present invention, the term comprises all types of plant and animal components" (col. 18-19). At column 19, specifically-recited types of feedstuffs include meat and bone meal from animals, hydrolyzed feathermeal, brewers grains, corn, grass silage, peanut meal, safflower meal, sunflower meal, soybeans and soybean hulls, wheat bran and wheat grain, and distiller's grain barley and distiller's grain corn. At the bottom of column 19, the reference states that "The invention comprises feedstuff as defined herein, in combination with a composition that inhibits prion formation. A composition of the invention is added to feedstuff and fed to an animal… The active component is added in an amount sufficient to 'treat' the animal. The amount will vary based on factors such as the type of animal and its size. In general, dosing is such that the animal will receive about 10 mg to about 10,000 mg/day/kg of weight of the animal."

Thus, it would have been obvious to one of ordinary skill in the art to have selected two or more of the various components as disclosed by Prusiner et al., for use in the composition to target specific proteins (prions). Prusiner et al. specifically suggest the use of such compositions containing protein denaturants, for use in protein-containing feedstuff compositions such as animal meal, various grain and oilseed meals, and specifically distiller's grains. The use of such compositions with dried distiller's grains (instant claim 28) would not have involved an inventive step, given such disclosure, and would

have been obvious to one of ordinary skill in the art who wished to provide such treatment to any form of distiller's grains.

Regarding instant claim 9, it would have been obvious to one of ordinary skill in the art to have utilized a "substantially airtight container" for the purposes of holding and transporting the protein-containing material, regardless of shape and dimensions. It is noted that since claim 9 depends from claim 7, none of the actual gases recited are required to be utilized, thus negating any flushing step. See also the notes, below.

It is appreciated that the reference discloses an objective that differs from applicant's, i.e. destroying and denaturing infectious proteins such as prions, versus "decreasing the degree of caking during storage or transport" as instantly claimed. However, the manner by which both the reference and the claimed invention go about achieving their respective stated result is actually the same; that of denaturing proteins contained in a proteinaceous product, by forming and applying a composition containing protein denaturants. The fact that applicant may have recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

NOTES:

- Regarding the dependent claims as directed to the addition/inclusion of an enzyme, "a material to assist in maintaining the reducing condition in the proteinaceous product," and/or "a material which assists in blocking of free sulfhydryl groups", it is noted that none of these claims actually *require* the presence of these materials, as the claims state that such materials may be present in amounts, for example, of "between about 0 ppm and about 5,000ppm", or "in an amount up to about 1000 ppm." See also the rejections under 35 USC 112 2nd paragraph, above.
- Upon future amendment of the claims to specifically require the inclusion of these materials, it is noted that these are also various forms of protein denaturants or co-materials which assist such conditions, and as such, would most likely be considered obvious under the statute of 35 U.S.C. 103(a).
- With regard to the applicability of the prior art, instant claim 21 does not further limit the claim(s) from which it depends, as the location and conditions of the proteinaceous product are irrelevant to the claimed invention, namely the composition. The claims do not specifically include the proteinaceous product.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEITH HENDRICKS
PRIMARY EXAMINER